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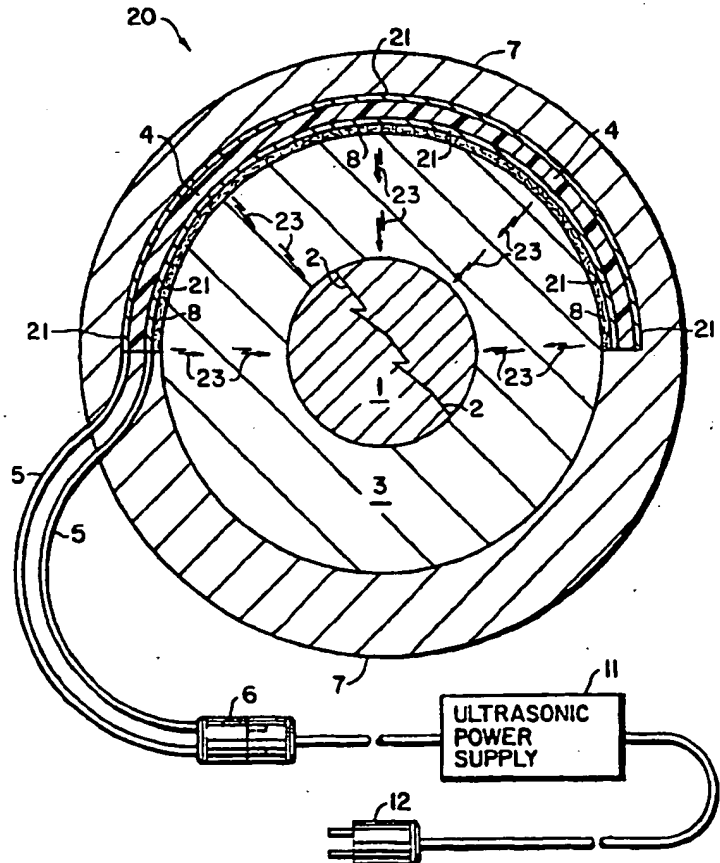
INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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| <p>(21) International Application Number: PCT/US94/07138 (22) International Filing Date: 24 June 1994 (24.06.94) (30) Priority Data: 08/099,585 30 July 1993 (30.07.93) US (60) Parent Application or Grant (63) Related by Continuation US 08/099,585 (CIP) Filed on 30 July 1993 (30.07.93) (71) Applicant (for all designated States except US): SONEX INTERNATIONAL CORPORATION [US/US]; Route 22, P.O. Box 533, Brewster, NY 10509 (US). (71)(72) Applicants and Inventors: BOCK, Robert, T. [US/US]; RD6 Drovers Lane, Brewster, NY 10509 (US). BATIZY, Levente, G. [US/US]; 2318 Lancaster Road, Akron, OH 44313 (US). MASIN, Richard [US/US]; 17410 Sugar Hill Trail, Chagrin Falls, OH 44023 (US). (74) Agent: DELUCA, John, P.; Watson, Cole, Grindle & Watson, Suite 1000, 1400 K Street, N.W., Washington, DC 20005 (US).</p> | | <p>(81) Designated States: JP, US, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE). Published <i>With international search report.</i></p> |

(54) Title: **ULTRASONIC BONE HEALING DEVICE**

(57) Abstract

A piezoelectric transducer (4) is located in conformal contact with the external anatomy (3) of a patient to cause, when energized, accelerated bone healing. The transducer (4) produces ultrasonic waves (23) and is secured in place by a windowless immobilizing cast (7) or a strap (50).



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ULTRASONIC BONE HEALING DEVICE

RELATED APPLICATIONS

This application is a Continuation-In-Part of U.S.
5 Patent Application Serial No. 08/099,585, filed July
30, 1993.

BACKGROUND OF THE INVENTION

This invention relates to bone healing devices.
10 More particularly, the invention is concerned with an
apparatus facilitating the use of ultrasonic energy
coupled to tissue to significantly accelerate bone
repair and healing.

Numerous attempts have been made in the past to
15 accelerate healing of bone by applying ultrasound to
the bone, both in animals and humans. The effect of
ultrasound has been demonstrated to accelerate fracture
and bone repair in the clinical and experimental
environments, where the application of ultrasound is
20 administered by highly skilled scientists and
physicians.

The approach taken to date applies the ultrasound
through the soft tissue to the bone by a rigid
piezoelectric transducer that is placed in a window of
25 the immobilizing cast, centered over the fracture site.
The window must be small to maintain immobilization of
the anatomy. Accordingly, relatively high intensity

ultrasound must be applied by a small transducer. To achieve adequate intensity, the currents necessary do not typically meet the accepted "low voltage, limited energy" standards of UL and other safety agencies.

5 Thus, excessive and expensive insulation technologies are required to maintain safety in face of such high voltages.

Treatment is typically applied daily for a period of about twenty minutes. To reduce, but not eliminate

10 the risk of window edema, a plug must be inserted into the cast window between the daily treatment periods. This opening and closing of the cast requires excellent dexterity, control and skill that is not easily acquired by laymen, and particularly the elderly.

15 Daily visits by nurses or visits to the clinic are required to avoid complications, infections and edema. The technology represented by the prior art is not suitable for widespread use and follow up care outside of a hospital or clinical environment.

20 What has occurred to date is that notwithstanding the teachings of the prior art, the ability to utilize ultrasound to speed up healing effectively, inexpensively and easily in a home environment, after the patient is released from the hospital, has remained

25 unsolved.

SUMMARY OF THE INVENTION

Responding to the above described unresolved needs, this invention provides a method of daily application of ultrasound while a full cast is placed
5 over the impacted anatomy, without any window for access for an ultrasound emitting device. The invention attains this goal by positioning a piezoelectric transducer onto the skin and applying the immobilizing cast over the transducer and the impacted
10 anatomy. A pair of wires connecting the transducer to the external ultrasonic power source is partially encapsulated by the cast and extends outside the cast with an appropriate connector installed onto the ends of the wires.

15 In one embodiment, the piezoelectric transducer comprises a flexible sheetlike structure which is conformable to the exterior anatomy. In another embodiment, the transducer is a rigid element secured to the anatomy by a flexible support.

20 The daily application of the ultrasonic treatment does not require any disassembly or disturbing of the cast. The patient simply connects the wires via a connector to the power source and initiates the daily application of ultrasonic treatments.

25 The present invention provides an electrically safe application of ultrasonic energy via a low voltage limited energy current.

The present invention also provides an inexpensive disposable ultrasonic transducer with an apparatus for attachment to an external ultrasonic power supply. The external power supply could be utilized by multiple patients in a hospital setting. The external power supply could also be reused by transferring to another patient after that the full course of treatment has been completed by one in a home environment.

Other objects and advantages will be apparent from the examination of the specification, drawings and claims.

BRIEF DESCRIPTION OF THE DRAWINGS

In the accompanying drawings, in which certain modes of carrying out the present invention are shown for illustrative purposes:

Fig. 1 is a cross-sectional illustration of the invention employing a flexible transducer secured about the exterior anatomy by an immobilizing cast;

Fig. 2 is an illustration of an alternative embodiment of the invention similar to the arrangement in Fig. 1 including an ultrasound transmitting gel interface with the skin and a gel seal;

Fig. 3 is a perspective view of the arrangement in Fig. 2;

Fig. 4 is a cross-sectional illustration of another embodiment of the invention where a transducer

is constructed from multiple pieces of rigid piezoelectric elements connected together by a flexible support to form a flexible transducer;

5 Fig. 5 is a perspective illustration in partial section illustrating an embodiment of the invention in a configuration where a rigid piezoelectric crystal is applied under an immobilizing cast;

Fig. 6 is a cross-sectional view of the arrangement of Fig. 5;

10 Fig. 7 illustrates in cross section another embodiment of the arrangement of Fig. 6; and

Fig. 8 illustrates an embodiment of the invention where a rigid piezoelectric transducer is attached to the anatomy by use of a flexible strap.

15

DESCRIPTION OF THE INVENTION

Referring in detail to the drawings, the reference numerals herein refer to the like numbered parts in the drawings. In the following discussion, unless
20 otherwise qualified, the term "ultrasound" refers to either continuous wave ultrasound or a repetitive burst type ultrasonic modality.

An ultrasonic healing device 20, in accordance with one exemplary form of the present invention, is
25 shown in Fig. 1. The healing device 20 comprises a sheetlike piezoelectric transducer 4 constructed of a flexible polymeric piezoelectric film, metallization 21

on the surfaces of the film to conduct electrical current into the film, connecting wiring 5 and connectors 6 that connect the healing device 20 to the external ultrasonic power supply 11. The external power supply draws its power from a standard household current source through a connector 12.

The flexible piezoelectric transducer 4 wraps around and conforms to the surface of the soft tissue 3 of the external anatomy surrounding the bone 1. The transducer 4 may be secured in position by the cast 7. To enhance transmission of the ultrasonic waves 23 into the tissue 3, a thin coating of gel 8 may be applied between the transducer 4 and the skin of the patient. To enhance safety, the transducer 4 should be large enough to completely wrap around the anatomy allowing the reduction of the driving voltage to the minimal levels. Thus, low voltage limited energy current driving the piezoelectric transducer 4 is spread over the circumference of the tissue 3 and is focused onto the fracture 2 area of bone 1 resulting in a therapeutically effective ultrasonic energy that is localized at the fracture 2 area of bone 1.

An ultrasonic healing device 22, enhanced with a layer of gel 8 in bulk form and a dam 9 to contain the gel 8 is shown in Fig. 2. The gel 8 tends to compensate for skin and soft tissue 3 shrinkage during the treatment period and assures a continuous

conductive path for the ultrasonic waves 23 from the transducer 4 to the soft tissue 2. The dam 9 is firmly attached to the transducer 4 by an adhesive 25 and positioned between the soft tissue 3 and the transducer 4 to form a sealed chamber 13 to contain the gel 8. Dam 9 is constructed of a flexible and compressible material that is compressed by the cast 7 during the installation process. The material of dam 9 also possesses adequate memory to expand and maintain the seal when soft tissue 3 shrinkage occurs during the long term healing process thus protecting the gel 8 from evaporation and escape from the chamber 13.

Fig. 3 shows an axonometric view of the arrangement of Fig. 2 to further illustrate the sealing mechanism when the ultrasound transmitting gel 8 is used in bulk. This view demonstrates the continuous circumferential nature of the dam 9 to form the chamber 13 to house and retain the bulk form of gel 8. The adhesive 10 facing of the dam 9 further enhances the seal of the chamber 13 and secures the healing device 22 in position during the application of the cast 7.

Fig. 4 shows a flexible transducer 30 constructed of rigid piezoelectric elements 31 connected together mechanically by a flexible sheet 33 and electrically by the wires 5, for connection to an ultrasonic frequency current supply via connector 6. In a simplified arrangement, the flexible sheet 33 may be eliminated

and the individual piezoelectric elements 31 may be placed onto the anatomy and secured in place by an immobilizing cast.

5 Figs. 5 and 6 show an ultrasonic bone healing device 40 in perspective and cross sectional views. The healing device 40 comprises a piezoelectric transducer 44 constructed of a rigid PZT crystal embedded under immobilizing cast 7, connecting wiring 5 and connectors 6 that connect the healing device 40
10 to the external ultrasonic power supply 11. The external power supply draws its power from a standard household current supply through a connector 12 or alternatively is powered by a battery which may be rechargeable.

15 The piezoelectric transducer 44 may be attached to the skin of the patient by a double backed tape 48 having matching acoustic impedance characteristics to the transducer 44 and to the soft tissue 3. The tape 48 holds the transducer 44 in contact with the soft
20 tissue 3 regardless of any shrinking of the soft tissue 3 under the cast 7 during the immobilization period. The transducer 44 may be backed up by a closed cell sponge 49 which is compressed by the cast 7 during the installation procedure. The sponge 49 thereby acts as
25 a spring to urge press the transducer 44 against the soft tissue 3 and to maintain a contact between the transducer 44 and the soft tissue 3 in the event that

the soft tissue 3 shrinks away from the cast 7 during the immobilization period. The closed cell sponge 49 may be designed with an acoustic impedance characteristic mismatched with the transducer 44 thereby reducing ultrasonic output of the transducer 44 toward the sponge 49. The ultrasonic waves 23 created by the transducer 44 may then be effectively focused and transmitted through the soft tissue 3 into the bone 1 to accelerate the healing of the fracture 2.

Fig. 7 shows an alternative construction where the transducer 44 may be secured under the cast by a heavy duty surgical tape 43 which is designed with a mismatched acoustic impedance characteristic of the transducer 44 thereby reducing ultrasonic output of the transducer 44 toward the surgical tape 43 and away from the bone fracture 2. The ultrasonic waves 23 created by the transducer 44 are thereby effectively focused and transmitted through the soft tissue 3 into the bone 1 to accelerate the healing of the fracture 2.

Fig. 8 shows an arrangement where the ultrasonic transducer 44 is attached to the skin by a double backed tape 48 and secured under a flexible strap 50.

While the preceding description contains many specificities, these should not be construed as limitations on the scope of the invention, but rather as an exemplification of a preferred and additional embodiments thereof. Many other variations are

possible. Skilled artisans will readily be able to change dimensions, shapes and construction materials of the various components described in the embodiments and adopt the invention to all types of sonic energy applications, from subsonic through sonic to the ultrasonic range. Accordingly, the scope of the invention should be determined not by the embodiments illustrated, but by the appended claims and their legal equivalents.

5

10

WHAT IS CLAIMED IS:

1 1. An apparatus for accelerating the process of
2 bone healing in a patient for use between a windowless
3 immobilizing cast and external anatomy soft tissue
4 surrounding the bone of the patient comprising:

5 a sheetlike piezoelectric transducer constructed
6 of at least one active flexible elongated element
7 having free end portions capable to spatially conform
8 to the soft tissue exterior anatomy of the patient,
9 said piezoelectric transducer contracting and expanding
10 volumetrically when energized and generating
11 corresponding vibrations of ultrasonic frequency
12 energy;

13 securing means associated with the immobilizing
14 cast coupled to said flexible piezoelectric transducer
15 to secure said flexible piezoelectric transducer in
16 place; and

17 electrical conductor means coupled to the
18 piezoelectric transducer extending from under the
19 securing means externally thereof.

1 2. The apparatus of claim 1 further comprising
2 means located between the soft tissue and the
3 piezoelectric transducer to enhance transmission of
4 ultrasonic energy from said piezoelectric transducer to
5 the bone.

1 3. The apparatus of claim 1 further comprising
2 means coupled to the piezoelectric transducer to hold
3 and retain a volume of soft ultrasonic energy
4 transmitting media between the transducer and the soft
5 tissue to cause the filling of gaps therebetween to
6 enhance the transmission of ultrasonic frequency
7 energy.

1 4. The apparatus of claim 3 further comprising
2 means for generating ultrasonic frequency electrical
3 signals connected to said coupling means to energize
4 said piezoelectric transducer.

1 5. A bone healing apparatus for use within a
2 windowless immobilizing cast, comprising:
3 a piezoelectric transducer constructed of at least
4 one active element having free ends;
5 flexible means to secure the active element
6 externally of the anatomy, said flexible means being
7 capable to spatially conform to the external anatomy,
8 said piezoelectric transducer contracting and expanding
9 volumetrically when energized for generating vibrations
10 of ultrasonic frequency energy; and
11 coupling means coupled to the piezoelectric
12 transducer extending from under the flexible means.

1 6. The apparatus of claim 5 further comprising
2 means located between the soft tissue and the
3 piezoelectric transducer to enhance transmission of
4 ultrasonic energy.

1 7. The apparatus of claim 5 further comprising an
2 ultrasonic transmitting medium and means coupled to the
3 piezoelectric transducer to hold and retain a volume of
4 said medium between the transducer and the soft tissue
5 to cause the filling of gaps therebetween.

1 8. The apparatus of claim 7 further comprising
2 generating means coupled to the piezoelectric
3 transducer for generating ultrasonic frequency
4 electrical signals to energize said piezoelectric
5 transducer.

1 9. The apparatus of claim 5 wherein the active
2 element has a relatively large distributed surface
3 area.

1 10. The apparatus of claim 5 wherein the active
2 element comprises a plurality of rigid transducer
3 elements disposed on the flexible means in spaced
4 adjacent relationship, said flexible means being
5 conformable with the soft tissue of the patient.

1 11. The apparatus of claim 5 wherein the active
2 element comprises a flexible sheet member of organic
3 piezoelectric material and at least one pair of
4 electrodes disposed on opposite sides of the sheet
5 member for producing when energized an electrical field
6 therebetween.

1 12. A method of accelerating bone healing
2 comprising the steps of: disposing a piezoelectric
3 transducer conformably about the external soft tissue
4 adjacent the bone, said transducer when energized for
5 focusing ultrasonic vibrational energy towards the
6 bone.

1 13. The method of claim 12 further comprising the
2 steps of immobilizing the bone within a windowless
3 immobilizing cast, and securing the transducer in
4 position adjacent soft tissue within the immobilizing
5 cast.

1 14. The method of claim 12 further comprising
2 energizing the piezoelectric transducer for producing
3 said ultrasonic vibrational energy.

1 15. A bone healing apparatus comprising: a
2 flexible piezoelectric transducer constructed of at
3 least one active element having free ends, and being

4 capable to spatially conform to the soft tissue
5 external anatomy adjacent the bone contracting and
6 expanding volumetrically when energized for generating
7 vibrations of ultrasonic frequency energy and being
8 operative when energized to transmit said vibrations
9 through the soft tissue of the anatomy to the bone
10 within the soft tissue.

1 16. An apparatus for accelerating the process of
2 bone healing in a patient for use within a windowless
3 immobilizing cast to transmit ultrasonic frequency
4 acoustic vibrations through the external soft tissue to
5 the bone of the patient comprising:

6 a piezoelectric transducer including at least one
7 active element contracting and expanding volumetrically
8 when energized in response to a changing electrical
9 field and generating vibrations of ultrasonic energy,
10 said transducer being operative to transmit said
11 vibrations through the soft tissue towards the bone;

12 means coupled to said piezoelectric transducer
13 having acoustic impedance approximately matching the
14 acoustic impedance of said piezoelectric transducer to
15 secure and couple the said piezoelectric transducer in
16 place about the said soft tissue; and

17 coupling means coupled to the said piezoelectric
18 transducer extending from under the said windowless
19 immobilizing cast.

1 17. The apparatus of claim 16 further comprising
2 means attached to a back side of the transducer to
3 reduce the output of said piezoelectric transducer said
4 means being spaced from the anatomy thereby effectively
5 focusing the ultrasonic output of said piezoelectric
6 transducer into the anatomy.

1 18. The apparatus of claim 16 further comprising
2 flexible means located between the piezoelectric
3 transducer and the immobilizing cast surrounding the
4 external anatomy to maintain contact between the said
5 piezoelectric transducer and said anatomy in the event
6 of shrinkage of said anatomy away from the said
7 immobilizing cast.

1 19. An apparatus for accelerating the process of
2 bone healing in a patient for use with a flexible strap
3 to transmit ultrasonic frequency acoustic vibrations
4 through the external soft tissue to the bone of the
5 patient comprising:

6 a piezoelectric transducer including at least one
7 active element contracting and expanding volumetrically
8 when energized in response to a changing electrical
9 field and generating vibrations of ultrasonic energy,
10 said transducer being operative to transmit said
11 vibrations through the soft tissue towards the bone;

12 means coupled to said piezoelectric transducer
13 having acoustic impedance approximately matching the
14 acoustic impedance of said piezoelectric transducer in
15 place about the said soft tissue; and
16 coupling means coupled to the said piezoelectric
17 transducer extending from under the said flexible
18 strap..

1 20. The apparatus of claim 19 further comprising
2 means attached to a back side of the transducer for
3 reducing the output of said piezoelectric transducer
4 said means being spaced from the anatomy thereby
5 effectively focusing the ultrasonic output of said
6 piezoelectric transducer into the said anatomy.

FIG. 1

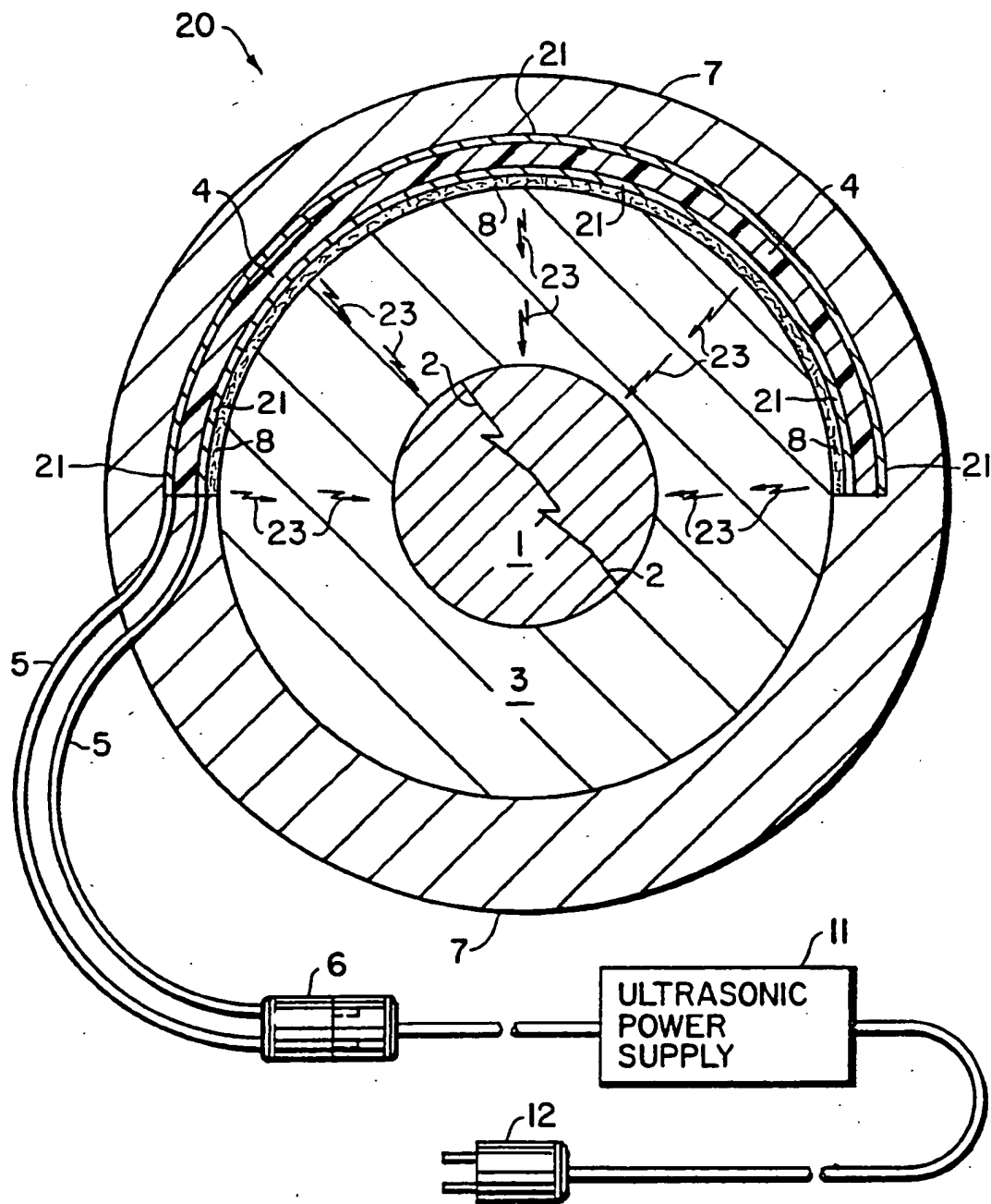


FIG.2

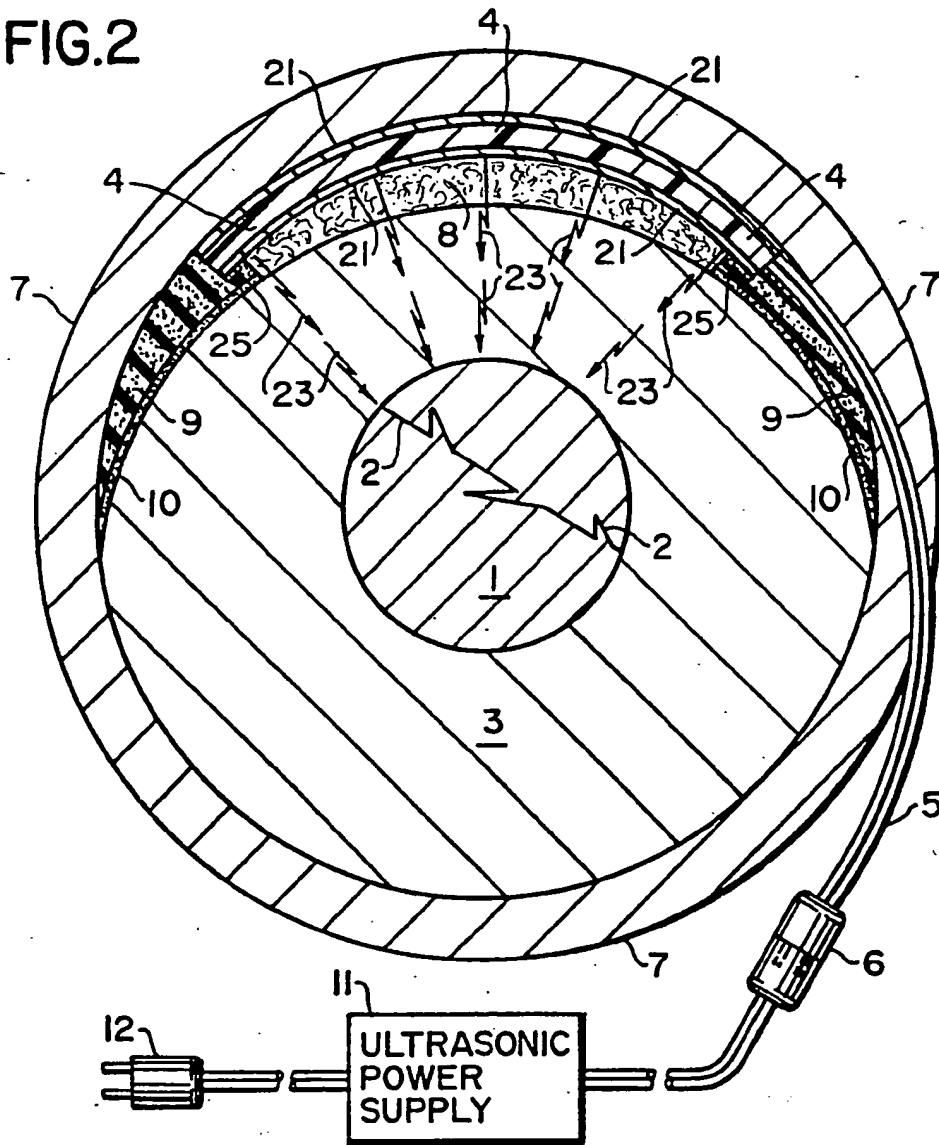
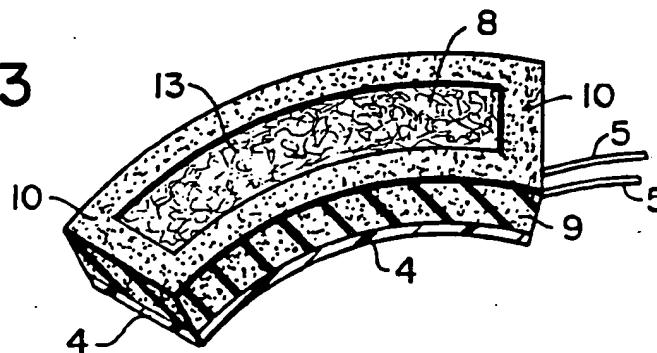


FIG.3



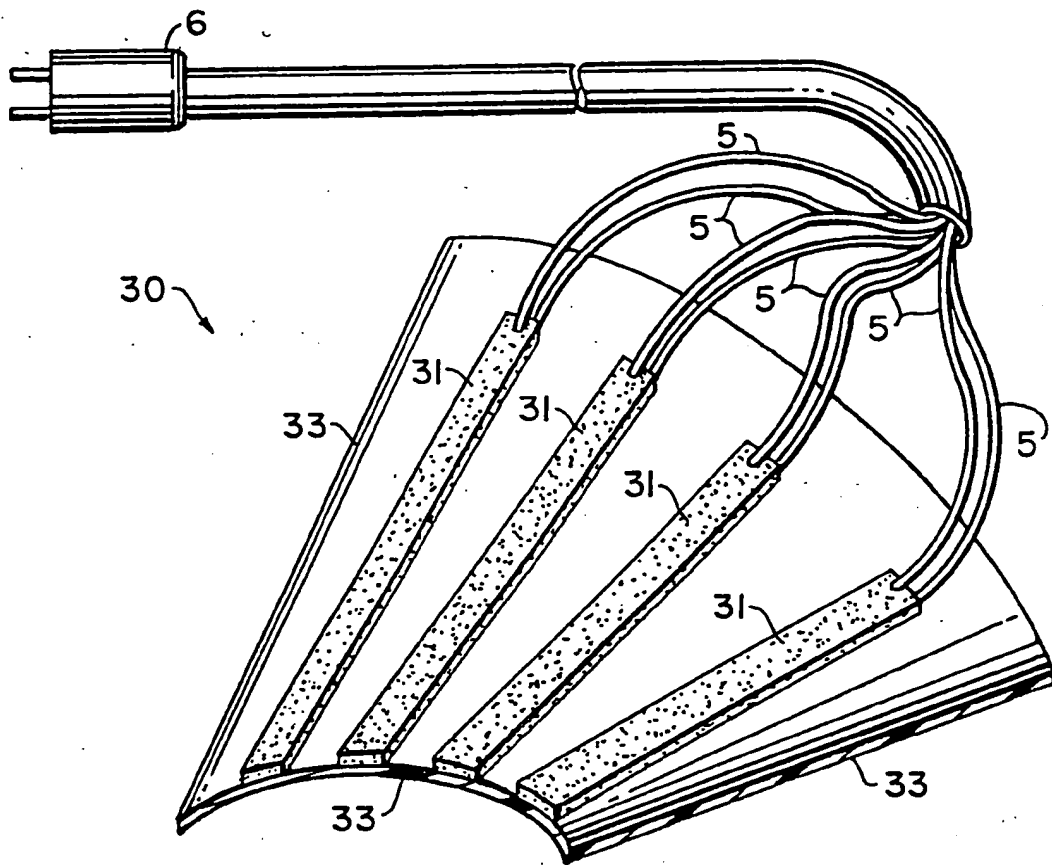


FIG.4

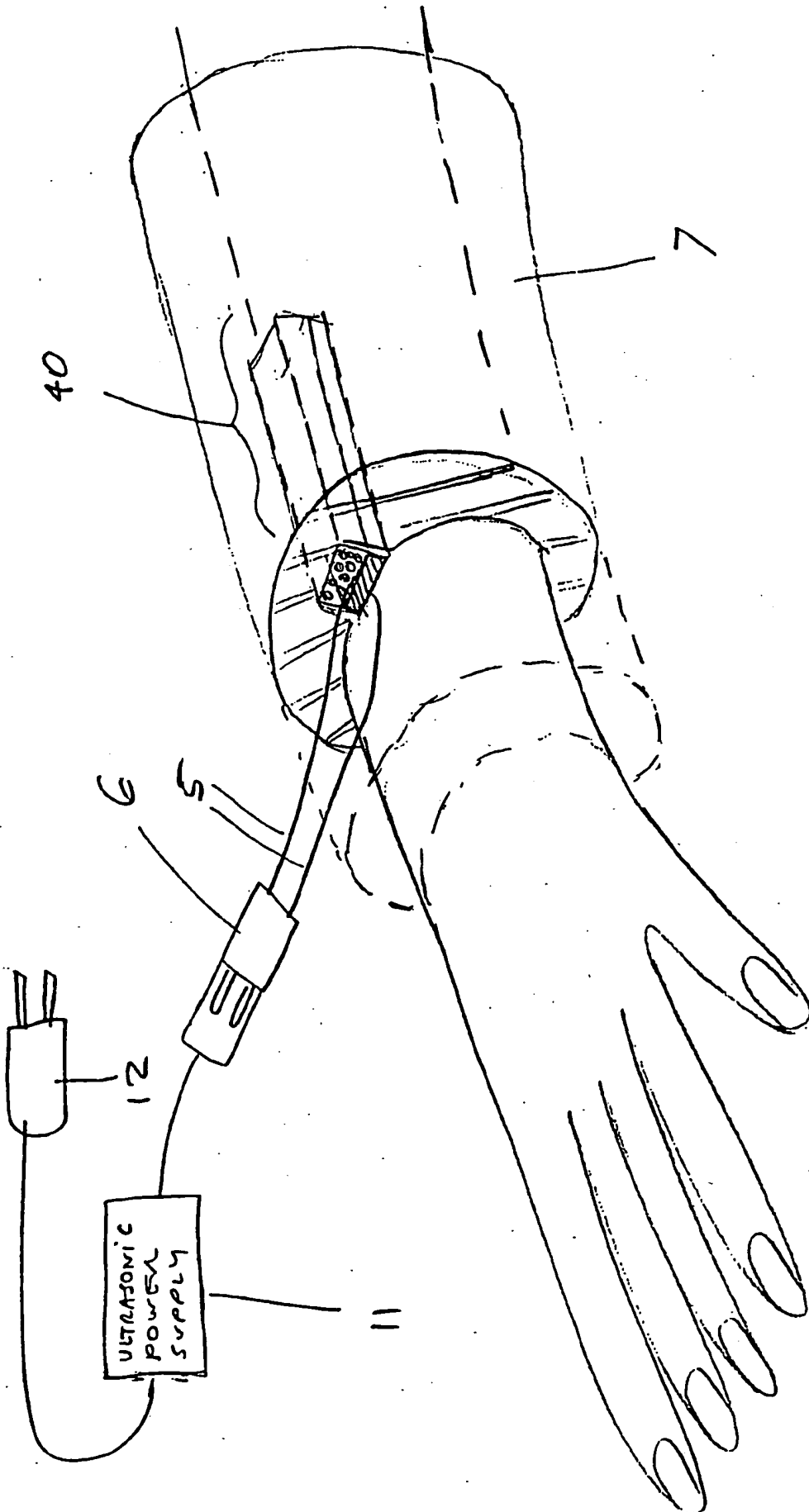


Fig. 5

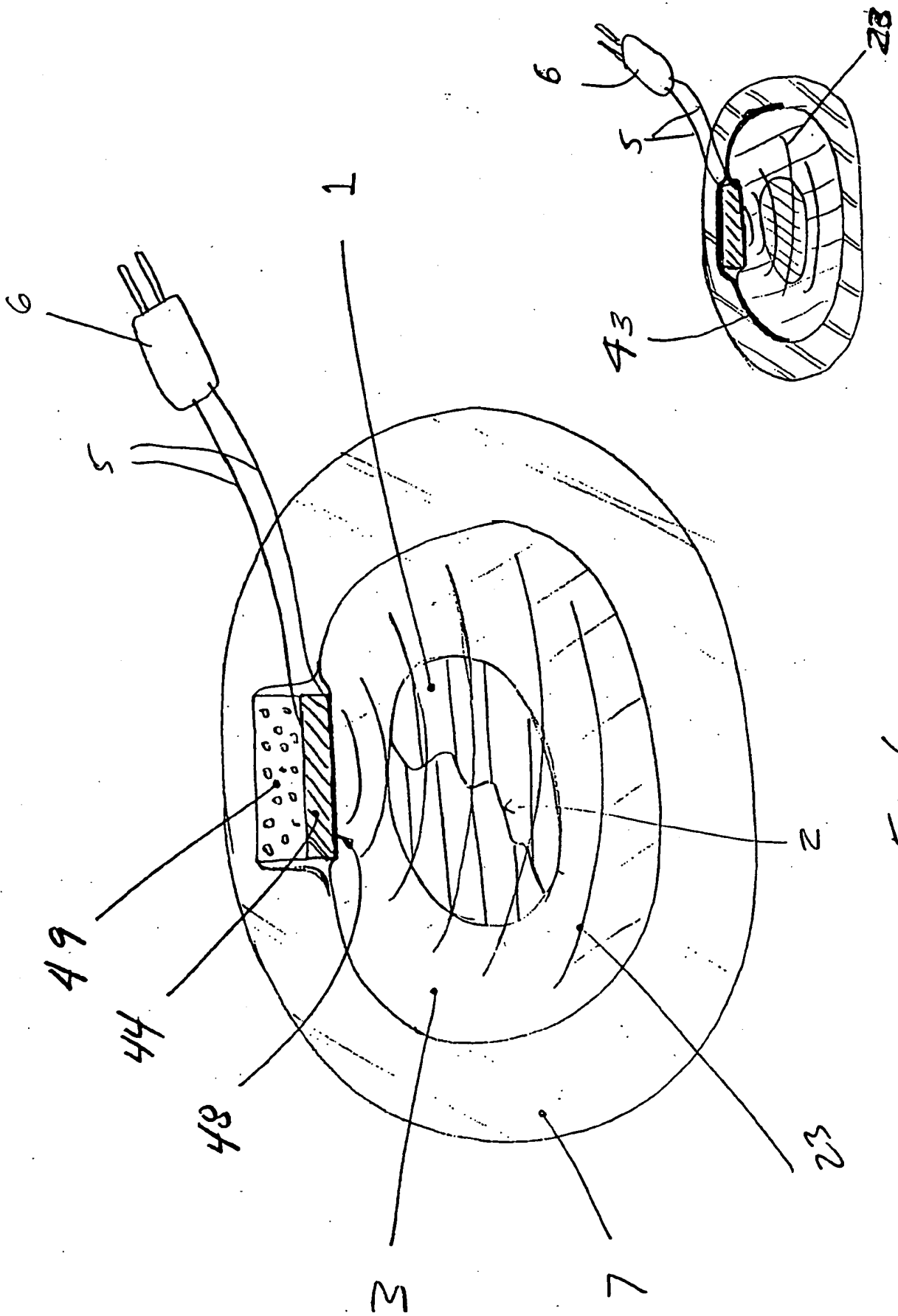
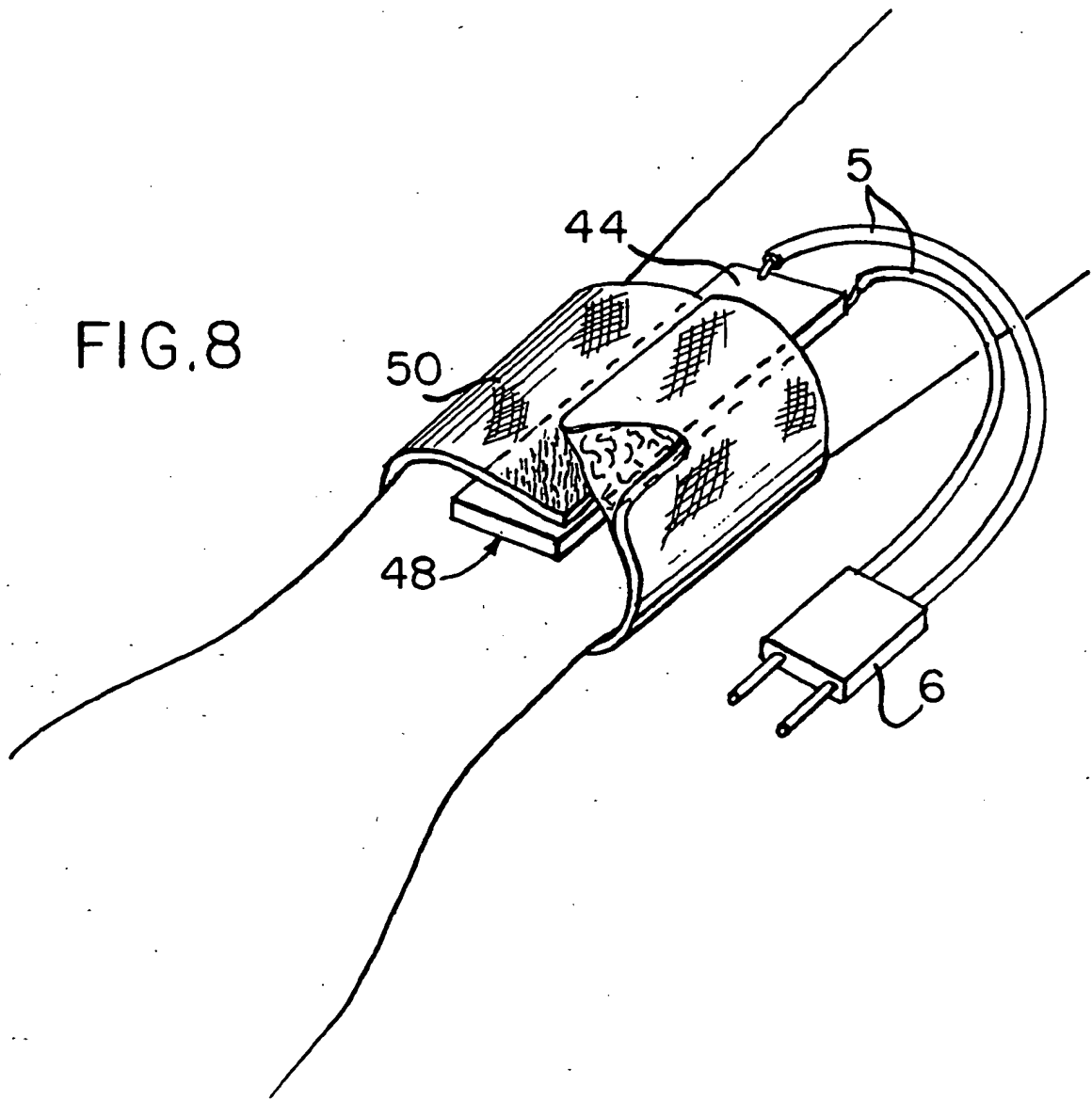


FIG. 7

FIG. 6

FIG. 8



INTERNATIONAL SEARCH REPORT

International application No.
PCT/US94/07138

A. CLASSIFICATION OF SUBJECT MATTER
 IPC(5) :A61B 17/56
 US CL :601/2
 According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED
 Minimum documentation searched (classification system followed by classification symbols)
 U.S. : 128/660.01, 660.03, 662.03, 662.06, 663.01; 601/2, 3; 607/3, 51, 97

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C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|-----------|--|-----------------------|
| X | US, A, 5,135,001, (SINOFSKY ET AL.), 04 August 1992. See entire document. | 15 |
| X | US, A, 5,211,160, (TALISH ET AL.), 18 May 1993. See entire document. | 5-9, 12-14, 19, 20 |

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